

**Response**

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Serial No.: 10/626,142

Confirmation No.: 9324

Filed: 24 July 2003

For: DENTAL WHITENING COMPOSITIONS AND METHODS

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**Remarks**

The Office Action mailed 25 January 2006 has been received and reviewed. No claims having been added, amended, or canceled, the pending claims are claims 1-80. Reconsideration and withdrawal of the rejections are respectfully requested.

**Rejection under 35 U.S.C. §112, First Paragraph*****WRITTEN DESCRIPTION***

The Examiner rejected claims 1-6, 8-12, 14-20, 22-27, 29, 46-49, and 57-72 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that the specification lacks adequate written description for the phrase "fluoride releasing group." Applicants respectfully disagree.

"To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." M.P.E.P. §2163(I). "An applicant may . . . show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." M.P.E.P. §2163(II)(A)(3)(a).

The presently rejected claims recite, among other things, polymers including a repeating unit including a fluoride releasing group. The specification recites that

[s]uitable fluoride *releasing groups include fluoride salts* as disclosed, for example, in U.S. Pat. Nos. 5,607,663 (Rozzi et al.), 5,662,887 (Rozzi et al.), 5,866,630 (Mitra et al.), 5,876,208 (Mitra et

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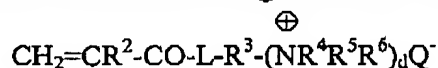
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al.), 5,888,491 (Mitra et al.), and 6,312,668 (Mitra et al.). A *preferred fluoride releasing group includes tetrafluoroborate anions* as disclosed, for example, in U.S. Pat. No. 4,871,786 (Aasen et al.). A preferred repeating unit of a fluoride releasing group includes trimethylammoniummethyl methacrylate. (Page 11, lines 21-27; emphasis added).

Applicants respectfully submit that it would be clear to one of skill in the art that salts that include, for example, fluoride anions and/or tetrafluoroborate anions can be fluoride releasing groups. Applicants further note that the recited patents were incorporated by reference at page 32, lines 1-3, which recites that "[t]he complete disclosures of the patents, patent documents, and publications cited herein are incorporated by reference in their entirety as if each were individually incorporated."

Further, Applicants respectfully submit that the specification describes monomers that include fluoride releasing groups by complete or partial chemical structure. For example, the specification describes

ammonium monomers of the general formula:



where  $\text{R}^2$ ,  $\text{R}^3$ ,  $\text{R}^4$ ,  $\text{R}^5$ , L and d are as defined above, and where  $\text{R}^6$  is H or alkyl of 1-12 carbon atoms and  $\text{Q}^-$  is an organic or inorganic anion. Preferred examples of such monomers include 2-N,N,N-trimethylammonium ethyl (meth)acrylate, 2-N,N,N-triethylammonium ethyl (meth)acrylate, 3-N,N,N-trimethylammonium propyl (meth)acrylate, N(2-N',N',N'-trimethylammonium) ethyl (meth)acrylamide, N-(dimethyl hydroxyethyl ammonium) propyl (meth)acrylamide, or combinations thereof, where the counterion may include fluoride" (page 10, lines 17-28).

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Applicants respectfully submit that it would be clear to one of skill in the art that such ammonium monomers could include fluoride releasing groups (e.g., fluoride as the counterion).

In addition, Applicants submit that it would be clear to one of skill in the art that salts that include, for example, fluoride anions and/or tetrafluoroborate anions can function to release fluoride into the oral environment.

In view of the remarks presented herein, Applicants respectfully submit that fluoride releasing groups are adequately described by structure, other physical and/or chemical properties, and functional characteristics to satisfy the written description requirement under 35 U.S.C. §112, first paragraph.

Applicants do not understand the Examiner's intent for stating that "the instant Specification points to US Patent No. 5,607,663 and US Patent No. 6,312,668 for suitable fluoride releasing groups both of which contain virtually the same language cited as art over the instant claims and argued by Applicant" (page 5, last full paragraph of the Office Action mailed January 25, 2006). Applicants have not argued that U.S. Patent Nos. 5,607,663 and 6,312,668 lack a disclosure of fluoride releasing groups. In the event that this rejection is not withdrawn, Appropriate clarification of the Examiner's statement is requested in the next Official Communication.

Finally, Applicants are unclear as to the intent of the Examiner's assertion that "the recitation of 'fluoride releasing group' is not *enabled* by the Specification to one of ordinary skill in the art" (page 5, last full paragraph of the Office Action mailed January 25, 2006; emphasis added). Whether or not the presently claimed subject matter was described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (i.e., enablement), is a requirement "separate and distinct" (see, for example, M.P.E.P. §2162) from the written description requirement under 35 U.S.C. §112, first paragraph.

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In view of the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-6, 8-12, 14-20, 22-27, 29, 46-49, and 57-72 under 35 U.S.C. §112, first paragraph, for lack of written description.

*ENABLEMENT*

The Examiner rejected claims 1-6, 8-12, 14-20, 22-27, 29, 46-49, and 57-72 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner alleged that because the specification, while being enabling for a dental whitening composition comprising trimethylammoniummethyl methacrylate tetrafluoroborate as a fluoride releasing group that performs unexpectedly better than the prior art, does not reasonably provide enablement for all fluoride releasing agents outside of those disclosed in EP 0363095 to Minnesota Manufacturing and Mining Company (*sic*).

"A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." M.P.E.P. §2164.04. "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." M.P.E.P. §2164.01(b). "For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be *used* in that manner without undue experimentation. Proof of enablement will be

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required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not *use* the genus as a whole without undue experimentation." M.P.E.P. §2164.02, paragraph entitled "WORKING EXAMPLES AND A CLAIMED GENUS" (emphasis added).

The specification clearly recites that methods of making the claimed polymers that include, among other things, a repeating unit including a fluoride releasing group are well known in the art and include, for example, free radical polymerization conditions as disclosed, for example, in U.S. Pat. Nos. 5,607,663 (Rozzi et al.), 5,662,887 (Rozzi et al.), 5,866,630 (Mitra et al.), 5,876,208 (Mitra et al.), 5,888,491 (Mitra et al.), and 6,312,668 (Mitra et al.) (e.g., page 8, lines 14-18). Although not required, and as admitted by the Examiner, Applicants have even provided working examples of the claimed polymers that include, among other things, a repeating unit including a fluoride releasing group (e.g., pages 24-27). Further, the specification provides methods of using the claimed polymers that include, among other things, a repeating unit including a fluoride releasing group (e.g., pages 20-22). Notably, the Examiner has not provided any reason to doubt the objective truth of the disclosure provided in the specification.

Applicants respectfully submit that one of skill in the art, using the disclosure provided in the specification (including the working examples), would be able to make and use the entire scope of the invention as recited in, for example, independent claims 1, 8, 15, 23, and 46-49. For example, the specification provides guidance to one of skill in the art in selecting as fluoride releasing groups, groups that include, for example, fluoride anions and/or tetrafluoroborate anions (e.g., page 11, lines 21-27).

Nonetheless, the Examiner alleged "that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented" (page 8, lines 8-10 of the Office Action mailed January 25, 2006). Applicants earnestly disagree.

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Applicants respectfully submit that the present specification would adequately enable one of skill in the art to make and use the claimed polymers that include, among other things, a repeating unit including a fluoride releasing group without undue experimentation for at least the reasons discussed herein above.

Further, the Examiner appears to be focusing on cases involving *physiological activity* in which "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved," citing *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970), in which the claims at issue recited *potency*. However, Applicants are not claiming *physiological activity or potency involving fluoride release*. Thus, Applicants respectfully submit that the Examiner's analysis concluding undue experimentation is inapposite the present claims.

Moreover, Applicants do not understand the Examiner's statement, in discussing fluoride releasing groups, "that trimethylammoniummethyl methacrylate tetrafluoroborate works better than another fluoride releasing group; dimethylhexadecylammoniummethyl methacrylate bromide" (page 7, paragraph 4 of the Office Action mailed January 25, 2006). Applicants can find no support for such a statement in the present specification. In fact, because dimethylhexadecylammoniummethyl methacrylate bromide does not contain any fluoride or fluorine, dimethylhexadecylammoniummethyl methacrylate bromide cannot be a fluoride releasing group.

Finally, in discussing U.S. Patent No. 6,312,668 (Mitra et al.) and EP 0363095 A2, the Examiner acknowledged that "[b]oth references are directed to polymeric dental compositions which provide fluoride to the oral cavity. As stated in EP 0363095 on page 2 beginning on line 13, fluoride use in the dental industry is well known. Therefore, one skilled in the art looking to include a fluoride-releasing component to a dental care composition would expect success by substituting one fluoride component for another that has been taught as effective in a like composition and wherein the like composition is directed to the same use." (Page 4, last paragraph of the Office Action mailed July 19, 2005). Applicants respectfully submit that the

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Examiner's position on the record is incongruous with the present rejection of claims 1-6, 8-12, 14-20, 22-27, 29, 46-49, and 57-72 for lack of enablement with respect to fluoride releasing groups.

For at least the reasons discussed herein above, Applicants respectfully submit that the Examiner has not advanced adequate reasons to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

In view of the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-6, 8-12, 14-20, 22-27, 29, 46-49, and 57-72 under 35 U.S.C. §112, first paragraph, for lack of enablement.

**Rejection under 35 U.S.C. §102**

The Examiner rejected claims 1-3, 23-25, 30-32, 46, 49-50, 53-56, and 65-72 under 35 U.S.C. §102(b) as being anticipated by EP 0363095 A2 to Minnesota Manufacturing and Mining Company (*sic*). This rejection is respectfully traversed.

Claims 1-3 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *a tooth whitening agent* and *a polymer* that includes a repeating unit including a polar or polarizable group, and a repeating unit including a fluoride releasing group, with the proviso that the polymer does not include pendant ethylenically unsaturated moieties. Claim 46 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 1; and claims 53-56 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 1.

Claims 23-25 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *a tooth whitening agent* and *a polymer* that includes a repeating unit including a polar or polarizable group, and a repeating unit including a fluoride-releasing group including tetrafluoroborate anions. Claim 49 is directed to a coating on hard

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tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 23; and claims 65-68 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 23.

Claims 30-32 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *a tooth whitening agent* and *a polymer* that includes a repeating unit including a polar or polarizable group, and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof, with the proviso that the polymer does not include pendant ethylenically unsaturated moieties. Claim 50 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 30; and claims 69-72 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 30.

Applicants respectfully submit that EP 0363095 A2 fails to disclose or suggest the combination of *a tooth whitening agent* with *a polymer* as recited in the above-referenced claims.

Specifically, EP 0363095 A2 discloses a "polymerizable composition which releases fluoride to dental tissue and which comprises one or more polymerizable monomers" (page 2, lines 44-45). However, EP 0363095 A2 fails to clearly and unequivocally disclose *a tooth whitening agent*.

Nonetheless, the Examiner noted that "the EP 0363095 reference teaches peroxides which after application to the tooth are exposed to light" (page 9, bottom two lines of the Office Action mailed January 25, 2006). The only reference to a peroxide located by Applicants Representatives is as follows:

Typically the compositions of the invention will be capable of free radical polymerization. Accordingly, they will comprise a polymerization initiation system such as an organic peroxide either



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alone or preferably in combination with a suitable amine, sulfide, thiol, phosphine or other such compound capable of producing radicals via reaction with the peroxide. Alternatively, the compositions may comprise a photoinitiation system such as a ketone or an alpha diketone, either alone or preferably in combination with a suitable amine, peroxide, sulfide, thiol, phosphine or other such compound capable of being sensitized by or otherwise reacting with the carbonyl compound to initiate free radical polymerization of the composition upon exposure to light. (Page 7, lines 47-54).

Thus, EP 0363095 A2 discloses that compositions of the present invention (i.e., polymerizable compositions that include one or more polymerizable monomers) can include a polymerization initiation system that can include, among other things, a peroxide. However, EP 0363095 A2 fails to disclose or suggest *a peroxide* with *a polymer* as recited in the presently rejected claims.

For at least this reason, Applicants respectfully submit that claims 1-3, 23-25, 30-32, 46, 49-50, 53-56, and 65-72 are not anticipated by EP 0363095 A2. Reconsideration and withdrawal of the rejection under 35 U.S.C. §102 are respectfully requested.

**Rejection under 35 U.S.C. §103**

The Examiner rejected claims 1-80 under 35 U.S.C. §103(a) as being unpatentable over EP 0363095 A2 to Minnesota Manufacturing and Mining Company (*sic*) and further in view of Huang et al. (U.S. Patent No. 6,083,421). This rejection is respectfully traversed.

The deficiencies of EP 0363095 A2 as applied to claims 1-3, 23-25, 30-32, 46, 49-50, 53-56, and 65-72 have been discussed herein above in the traverse of the rejection under 35 U.S.C. §102. Claims 4-7, 26-29, and 33-36 depend therefrom. In brief, EP 0363095 A2 fails to disclose or suggest the combination of *a tooth whitening agent* with *a polymer* as recited in present claims 1-7, 23-36, 46, 49-50, 53-56, and 65-72.

Claims 8-14 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *greater than 10% by weight of a tooth whitening agent*,

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based on the total weight of the dental whitening composition, and *a polymer* that includes a repeating unit including a polar or polarizable group, and a repeating unit including a fluoride releasing group. Claim 47 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that include a dental whitening composition as recited in claim 8; and claims 57-60 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 8.

Claims 15-22 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *a tooth whitening agent* and *a polymer* that includes a repeating unit including a polar or polarizable group and a repeating unit including a fluoride releasing group, with the proviso that the dental whitening composition does not include hydrogen peroxide. Claim 48 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 15; and claims 61-64 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 15.

Claims 37-40 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *greater than 10% by weight of a tooth whitening agent*, based on the total weight of the dental whitening composition, and *a polymer* that includes a repeating unit including a polar or polarizable group, and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof. Claim 51 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 37; and claims 73-76 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 37.

Claims 41-45 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *a tooth whitening agent* and *a polymer* that includes a repeating unit including a polar or polarizable group, and a repeating unit including a group

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selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof, with the proviso that the dental whitening composition does not include hydrogen peroxide. Claim 52 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 41; and claims 77-80 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 41.

Applicants respectfully submit, for reasons similar to those discussed herein above in the traverse of the rejection under 35 U.S.C. §102, that EP 0363095 A2 fails to disclose or suggest the combination of *a tooth whitening agent* with *a polymer* as recited in present claims 1-80.

Further, Applicants respectfully submit that Huang et al. fails to cure the deficiencies of EP 0363095 A2. Specifically, Huang et al. "relates to a tooth-whitening varnish composition, comprising 6-20% of carbamide peroxide, 2-9% of film forming agent and 77-88% of volatile organic solvent, based on the total weight of the composition. The volatile organic solvent is selected from ether, ethylacetate, ethyl alcohol, or acetone. The film forming agent is artificial or natural material selected from cellulose, polyvinyl, butyral, coumarone resin or shellac." (Abstract). However, Huang et al. fails to disclose or suggest the combination of *a tooth whitening agent* with *a polymer* as recited in present claims 1-80.

Thus, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability of claims 1-80 over EP 0363095 A2 in view of Huang et al.

The Examiner rejected claim 35 under 35 U.S.C. §103(a) as being unpatentable over EP 0363095 A2 to Minnesota Manufacturing and Mining Company (*sic*) as applied to claims 1-80 above taken with Lakshmanan (U.S. Patent No. 4,018,732). This rejection is respectfully traversed.

Claim 35 depends from claim 30. The deficiencies of EP 0363095 A2 as applied to claim 30 have been discussed herein above in the traverse of the rejection under 35 U.S.C. §102. In

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brief, EP 0363095 A2 fails to disclose or suggest the combination of *a tooth whitening agent* with *a polymer* as recited in present claim 30. Applicants respectfully submit that Lakshmanan provides nothing to correct the deficiencies of EP 0363095 A2. Thus, for at least this reason, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness of claim 35 over EP 0363095 A2 in view of Lakshmanan.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103 are respectfully requested.

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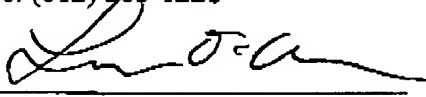
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Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted  
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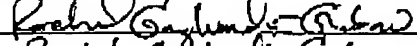
May 25, 2006  
Date

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 25<sup>th</sup> day of May 2006, at 12:53 p.m. (Central Time).

By:   
Name: Rachel Gaylini-Gebhardt

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